§ 25.32 Finding of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a finding of no significant impact (FONSI) is a document prepared by a Federal agency and stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) If the EA has been prepared by an applicant or petitioner, the agency may choose to include additional evidence in the FONSI. Any remaining unknowns or uncertainties will be identified.

(c) The agency official(s) responsible for the preparation and approval of the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusions not to prepare an EIS for the action under consideration.

§ 25.33 Notice of intent.

(a) As defined by CEQ regulations (40 CFR 1508.22), the Notice of Intent notifies the public that the agency has determined that an EIS will be prepared. This determination may be based on information contained in an EA or on other information available to the agency which indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the Notice of Intent will describe the proposed action, possible alternatives, the agency's proposed scoping process, which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings, and the identification of persons within the agency to contact for further information.

§ 25.34 Draft, final, and supplemental environmental impact statements.

(a) The CEQ regulations (40 CFR part 1502) provide detailed requirements for the preparation of an EIS. CEQ's format for EIS's (40 CFR 1502.10) will be followed unless the agency determines that there is a compelling reason to do otherwise.

(b) When chemical substances enter the environment as a result of a proposed action or other regulatory alternatives, the portion of the EIS format on *environmental consequences* (40 CFR 1502.10(g)) will include discussion of the environmental fates and effects of those substances similar to that described in § 25.31a.

(c) Any final EIS will contain any additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments as required in 40 CFR 1503, including any revisions resulting from comments or other information.

(d) Draft and final supplemental EIS's will conform to the EIS format (40 CFR 1502.10) unless there is a compelling reason to do otherwise.

Subpart D—Agency Decisionmaking

§ 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The NEPA process is an integral part of FDA's decisionmaking. Agency decisionmakers ensure that the policies and purpose of NEPA and CEQ regulations are complied with by:

(1) Completing or assuring the completion of an EA, determining whether an EIS is required and, ordinarily, completing a draft EIS (if one is required) prior to or at the time of proposing an action subject to §§ 25.21 and 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision as required by 40 CFR 1502.14. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.